

REMARKS

Claims 1-36 are currently pending in the application. By the amendment, only claim 19 has been amended.

Accordingly, reconsideration and withdrawal of the pending rejections are requested in view of the instant amendment and the accompanying remarks.

Acknowledgement of Receipt of Certified Documents

Applicant notes with appreciation the Examiner's consideration of the documents cited in the Information Disclosure Statement filed on October 28, 2003 by the return of the initialed and signed copy of the PTO-1449 Form accompanying the Information Disclosure Statement.

Drawings

As neither the Examiner nor the Patent Office Draftsperson has objected to the originally submitted drawings, Applicant understands that these drawings are acceptable.

Amendment Fully Supported by the Original Disclosure

The above amendment does not add new matter to the application and is fully supported by the specification. For example, support for amending independent claim 19 to recite, "*first anchoring member*" is provided at paragraphs [0003], [0011], [0012], [0014] and [0027] of the specification.

35 U.S.C. §102 Rejection**1. Over LEBNER**

Claims 1-3, 5, 9-11, 16, 19-21, 23, 27-29 and 34 are rejected under 35 U.S.C. § 102(b) as being anticipated by Lebner (US Patent No. 6,329,564) (hereafter "LEBNER"). Applicant respectfully traverses this rejection for at least the following reasons.

In order to establish a *prima facie* case of anticipation under 35 U.S.C. § 102, a single prior art reference must disclose each and every element as set forth in the subject claim. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ 2d 1051, 1053 (Fed. Cir. 1987). Applicant respectfully submits that a *prima facie* case of anticipation cannot be established because LEBNER fails to teach each and every element of the claims.

More particularly, Applicants' independent claim 1, recites, *inter alia*:

"c) means for attaching the one or more first connecting members to the second anchoring member and means for attaching the one or more second connecting members to the first anchoring member, the attachment of the connecting members to the anchoring members forming attached and bridging portions of the one or more connecting members, the attached portions being attached to an anchoring member, and the bridging portions spanning the over-laceration area between the first and second anchoring members, *the average width of the bridging portions being less than the average width of the attached portions*".

Applicants' independent claim 19, as currently amended recites, *inter alia*:

"(a)

iii) means for attaching the one or more first connecting members to the second anchoring member and means for attaching the one or more second connecting members to the first anchoring member, the attachment of the one or more first connecting members and the one or more second connecting members to the second and first anchoring

members, respectively, forming attached and bridging portions of the one or more connecting members, the attached portions being attached to an anchoring member, and the bridging portions spanning the over-laceration area between the first and second anchoring members, *the average width of the bridging portions being less than the average width of the attached portions*;

- (b) attaching the first and second components to the skin on opposite sides of the laceration or incision, the edge of the first and second components from which the one or more connecting members extend, being the edge closest to the laceration or incision;
- (c) closing the laceration or incision by adjusting the position of the first and second anchoring members relative to each other in both an X and a Y dimension; and".

Applicant submits that LEBNER does not disclose or even suggest, among other things, *the average width of the bridging portions being less than the average width of the attached portions*, as at least disclosed in independent claim 1 and claim 19, as currently amended. See Figures 3-6 and paragraphs [0045] to [0048] of Applicant's disclosure.

Applicant acknowledges, for example, that Fig. 3 of LEBNER merely shows the bandage of Fig. 1 in the tension and fixed or applied position. See Col. 6, lines 25-32. Further, the pulling elements 40 and 45 are not shown in Fig. 3, but in Fig. 1, the pulling elements 40 and 45 are shown so as to show the point of removal from connecting members 15 and 35 are along perforations 17 and 37. See Col. 6, line 27. Further, the LEBNER device discloses cut-outs 47 and 49 in the connectors 15 and 35 that are positioned directly above the incision. See Col. 6, lines 30-33. However, it is clear that this document does not specifically disclose that *the average width of the bridging portions being less than the average width of the attached portions*, to the contrary, Fig. 1 and Fig. 3 of LEBNER shows connecting members 15 and 35 having a constant

width.

Thus, LEBNER fails to provide any disclosure of the above-noted features at least recited in the independent claims.

Applicant submits, contrary to the present invention, the LEBNER cut-outs 47 and 49 in the connectors 15 and 35 do not change the overall width for connectors 15 and 35. The present invention discloses the bridging portions being less than the average width of the attached portions. More specifically, independent claim 1 and claim 19, as currently amended, set forth that, *inter alia, the average width of the bridging portions being less than the average width of the attached portions.* Applicant asserts that LEBNER does not disclose or even suggest the arrangement of the present invention as recited in the independent claims. In fact, by reducing the average width of the bridging portion of the connecting element relative to the attached portions, Applicant's present invention effectively maximizes the ability of a user to adjust the positioning of the first component relative to the second component, in a direction substantially parallel to the edges from which the connecting members extend. See paragraphs [0012] and [0016] of Applicant's disclosure. Additionally, for high tension wounds increasing the surface of the attached portions (as opposed to the constant width embodiments taught in the prior art) provides for greater adhesive surface area which provides for increased security of closure. See paragraphs [0006], [0007] and [0046] of Applicant's disclosure.

Because LEBNER fails to disclose each and every recited feature of at least independent claim 1 and claim 19, as currently amended, Applicant submits that the Examiner has failed to provide an adequate evidentiary basis to support an anticipation rejection under 35 USC § 102(b). Therefore, the 102(b) rejection of independent claim

1 and claim 19 as currently amended, should be withdrawn.

Further, Applicant submits that claims 1-3, 5, 9-11, 16, 19-21, 23, 27-29 and 34 are allowable at least for the reason that these claims depend from allowable base claims and because these claims recite additional features that further define the present invention.

Accordingly, Applicant requests that the Examiner reconsider and withdraw the rejection of the claims 1-3, 5, 9-11, 16, 19-21, 23, 27-29 and 34 under 35 U.S.C. § 102 (b) and indicate that these claims are allowable.

2. *Over PRELLER*

Claims 1-3, 10-11, 17, 19-21, 28-29 and 35 are rejected under 35 U.S.C. § 102(b) as being anticipated by Preller (US Patent No. 5,263,970) (hereafter "PRELLER"). Applicant respectfully traverses this rejection for at least the following reasons.

Applicant submits that in contrast to the requirement of 35 U.S.C. § 102(b), PRELLER does not disclose every element of the claimed invention. In this case, Applicant's independent claim 1 recites, *inter alia*:

"A two-component device for closing a laceration or incision, comprising:
a) a *first component* comprising a first adhesive-backed anchoring member and one or more first connecting members extending from one edge thereof in a first direction;
b) a *second component* comprising a second adhesive-backed anchoring member and one or more second connecting members extending from one edge thereof in a second direction generally opposite to the first direction; and
c) means for attaching the one or more first connecting members to the second anchoring member and means for attaching the one or more second connecting members to the first anchoring member, the attachment of the connecting members to the anchoring members forming attached and bridging portions of the one or more connecting members, the attached

portions being attached to an anchoring member, and the bridging portions spanning the over-laceration area between the first and second anchoring members, *the average width of the bridging portions being less than the average width of the attached portions.*".

Applicant's independent claim 19, as currently amended recites, *inter alia*:

"A method for closing a laceration or incision, the method comprising:
a) providing a two-component device for closing a laceration or incision, comprising:
a first component comprising an adhesive-backed anchoring member and one or more first connecting members extending from one edge thereof in a first direction;
a second component comprising a adhesive-backed anchoring member and one or more second connecting members extending from one edge thereof in a second direction generally opposite to the first direction; and
means for attaching the one or more first connecting members to the second anchoring member and means for attaching the one or more second connecting members to the first anchoring member, the attachment of the one or more first connecting members and the one or more second connecting members to the second and first anchoring members, respectively, forming attached and bridging portions of the one or more connecting members, the attached portions being attached to an anchoring member, and the bridging portions spanning the over-laceration area between the first and second anchoring members, *the average width of the bridging portions being less than the average width of the attached portions*;
b) attaching the first and second components to the skin on opposite sides of the laceration or incision, the edge of the first and second components from which the one or more connecting members extend, being the edge closest to the laceration or incision;
c) closing the laceration or incision by adjusting the position of the first and second anchoring members relative to each other in both an X and a Y dimension; and
d) fixing the relationship between the first and second anchoring members established in step c) by attaching the one or more first connecting members to the second anchoring member, and the one or more second connecting members to the first anchoring member."

While the Examiner asserts PRELLER discloses all the features of independent claim 1 and claim 19, as currently amended, Applicant submits that a review of PRELLER fails to support this assertion. Moreover, the Examiner failed to point out specific elements disclosed by PRELLER that assertively shows the recited features of the invention. In fact, nothing in PRELLER discloses or suggests the features of the present invention, as at least

recited in independent claim 1 and claim 19, as currently amended. In particular, PRELLER does not disclose or suggest, a *two-component device for closing a laceration or incision*, as at least recited in the independent claim 1 and claim 19, as currently amended.

Applicant notes that, PRELLER shows a surgical dressing 10 having a manipulating means 22 that interconnects locating members 12, 14, such that the manipulating means 22 and the locating members 12, 14 are a one piece article. See Abstract. Applicant submits PRELLER fails to teach a *two-component device for closing a laceration or incision*, as at least recited in Applicant's independent claim 1 and claim 19, as currently amended.

Applicant's two-component device offers numerous advantages over the single-component device of PRELLER. In particular, Applicant's two-component device comprises a first and a second component which are separate and distinct from one another. Each component is applied individually to either side of the wound or incision to be closed. The use of two independently positioned components enables the user to precisely align distinct wound edges on either side of the wound or incision to be closed. Unlike the single-component device of PRELLER, Applicant's two-component device provides clear visibility of the wound, and access to the wound during the closure process. Thus, the wound can be cleaned during and after the closure process, and dressings such as bacitracin may be applied. Furthermore, Applicant's claimed invention eliminates the potential problem of adhesive from the bandage making contact with wound area. As discussed above, PRELLER teaches a single, unitary device, such that PRELLER does not teach or suggest the above-noted features of Applicant's claimed invention.

Moreover, Applicant notes, that PRELLER also fails to disclose or even suggest, *the average width of the bridging portions being less than the average width of the attached*

portions, as at least recited in the independent claim 1 and claim 19, as currently amended.

Applicant notes that, PRELLER shows a surgical dressing 10 for closing a wound that includes a manipulating means 22 comprising of two sets of limb-like elements 24 and 26. The set 24 has a plurality of spaced limbs 24.1, as well as set 26 has a plurality of spaced limbs 26.1. Thus, PRELLER shows both limb-like elements 24 and 26 having a constant width for their entire length. See Figures 1 and 2 and Col. 2, lines 18-33. Applicant submits PRELLER fails to teach *the average width of the bridging portions being less than the average width of the attached portions*, as claimed in Applicant's invention.

Applicant respectfully submits that PRELLER shows the free ends of the limbs 24.1 and 26.1 of each set 24 and 26 having a tab portion 28 (see Figures 1 and 2 and Col. 2, lines 34-42). However, the tab portion 28 of PRELLER is an element added to the limbs 24.1 and 26.1, such that PRELLER does not teach or suggest the above-noted features of Applicant's claimed invention.

Furthermore, Applicant notes in particular, that PRELLER also fails to disclose, or even suggest, *means for attaching the one or more first connecting members to the second anchoring member and means for attaching the one or more second connecting members to the first anchoring member*, as at least recited in Applicant's independent claim 1 and claim 19, as currently amended.

Applicant submits that paragraph [0013] of the Specification recites, *inter alia*:

"Adhesive is a preferred means of attaching one or more connecting members to an anchoring member. In one embodiment, adhesive is applied to at least a portion of the lower surface of the connecting members for attaching the connecting members of one of the two components to the applied anchoring member of the other component. The connecting members have two parts or portions – an attached portion and a bridging portion. The attached portion of the connecting members, as the name

indicates, is that portion which is attached to the anchoring member of the opposing component following application of the device. The bridging portion is the portion of the connecting member or members which spans the over-laceration area. In further refined embodiments, the lower surface of the bridging portion contains less adhesive than the attached portion. In preferred embodiments, the entire bridging portion of the one or more connecting members are free of adhesive or alternately have adhesive, but this is blocked with another film (kill layer) to render the adhesive in the bridging portion nonfunctional.”.

Applicant notes that PRELLER shows two sets of limb-like elements 24 and 26, wherein set 24 has a plurality of spaced limbs 24.1, and set 26 has a plurality of spaced limbs 26.1. In particular, contrary to the Applicant’s claimed invention, Figures 3-5 of PRELLER shows the limbs (24.1 and 26.1) carrying a tab portion 28 having an operatively lower surface 30 with an adhesive coating material 32. See Col. 2, lines 34-43 of PRELLER. During the operative use of the dressing device 10, PRELLER teaches the backing sheets 34 (covering the coatings 32 of the tab portions 28 of the sets 24, 26) are removed, and then the backing sheets 36 (covering the adhesive coatings 35 on strips 12, 14) are also removed. PRELLER shows the tab portions 28 being fixed by the coating 32 to the strips 12, 14 via coating 35. See Figures 3-5 and Col. 2, lines 53-65 of PRELLER.

However, this is contrary to Applicant’s invention, since PRELLER shows the plurality of spaced limbs 24.1, 26.1 being attached by coating 32 to a tab portion 28, which further includes a coating 34 that attaches to strip 12, 14 via coating 35. Thus, the tab portion 28 of PRELLER is an element added to the limbs 24.1 and 26.1, such that PRELLER does not teach or suggest the above-noted features of Applicant’s claimed invention. Therefore, Applicant’s invention is not anticipated by the cited PRELLER reference.

Applicant further notes, that PRELLER again fails to disclose, or even suggest, *the*

attachment of the connecting members to the anchoring members forming attached and bridging portions of the one or more connecting members, the attached portions being attached to an anchoring member, and the bridging portions spanning the over-laceration area between the first and second anchoring members, as at least recited in the independent claim 1 and claim 19, as currently amended.

Finally, an additional point can be made with respect to rejected method claim 19. claim 19, as currently amended recites, *inter alia*:

- "c) closing the laceration or incision by adjusting the position of the first and second anchoring members relative to each other in both an X and a Y dimension; and
- d) fixing the relationship between the first and second anchoring members established in step c) by attaching the one or more first connecting members to the second anchoring member, and the one or more second connecting members to the second anchoring member.".

Applicant submits, contrary to the Examiner's assertions concerning independent claim 19, the PRELLER device operates in a different manner than the instant invention, such that the pulling elements 40 and 45 are temporarily attached to the connectors 15 and 35 by perforations 17, so as to position the device over the wound, resulting in the connectors 15 and 35 being equal distance from each other. See Figures 1-5 and Col. 2, lines 25-33 of PRELLER. However, the present invention provides a significant advantage over the PRELLER device by allowing for a very fine adjustment that can be made in the X and Y dimension so as to ensure the laceration closure has minimal scarring. See Figures 2-4 and paragraphs [0011] to [0012] of the Applicant's disclosure. Moreover, Applicant's claim invention provides the very fine adjustment for wounds having a non-uniform wound edge which produces a result of minimal scarring to the skin. In particular, by reducing the average width of the bridging portion of the connecting element relative to the attached portions, Applicant's present invention effectively maximizes the ability of a user to adjust

the positioning of the first component relative to the second component, in a direction substantially parallel to the edges from which the connecting members extend. See paragraphs [0012] to [0016] of Applicant's disclosure. Additionally, for high tension wounds increasing the surface of the attached portions (as opposed to the constant width embodiments as taught in the prior art) provide for greater adhesive surface area, which provides for increased security of closure. See paragraphs [0006], [0007] and [0046] of Applicant's disclosure. Contrary to the Applicant's claimed invention and the Examiners assertions, PRELLER teaches numerous closely-spaced filaments. For example, in column 2, lines 28-30 of PRELLER recites, *inter alia*: "Each limb 24.1, 26.1 is formed by mating and adhesively bonding corresponding extensions of strips 12, 14.". PRELLER teaches the limbs are drawn in opposite directions to close the wound (see Col. 2, lines 53-55), wherein the limbs adopt the position shown in Figure 5. See Figure 5 and Col. 2, lines 63-65. Such a design of PRELLER, at best, highly restricts the ability to adjust the initially applied flat flexible components laterally during wound closure. Applicant's use of spaced-apart filaments solves this problem associated with the cited prior art.

Because PRELLER fails to disclose each and every recited feature of at least independent claim 1 and claim 19, as currently amended, Applicant submits that the Examiner has failed to provide an adequate evidentiary basis to support an anticipation rejection under 35 USC § 102(b). Therefore, the 102(b) rejection of independent claims 1 and 19 should be withdrawn.

Further, Applicant submits that claims 1-3, 10-11, 17, 19-21, 28-29 and 35 are allowable at least for the reason that these claims depend from allowable base claims and because these claims recite additional features that further define the present invention.

Accordingly, Applicant requests that the Examiner reconsider and withdraw the rejection of the claims 1-3, 10-11, 17, 19-21, 28-29 and 35 under 35 U.S.C. § 102 (b) and indicate that these claims are allowable.

35 U.S.C. § 103 Rejection

Claims 4, 6-8, 12-15, 18, 22, 24-26 30-33 and 36 were rejected under 35 U.S.C. § 103(a) for being allegedly unpatentable over LEBNER in view of Baker (U.S. Patent No. 5,979,450) (hereafter “BAKER”).

The Examiner acknowledges that LEBNER lacks, among other things, a wound edge bar or a code on the components to distinguish the different parts from one another. However, the Examiner explains that BAKER teaches these features and that it would have been obvious to combine the teachings of these documents. Applicant respectfully submits that a *prima facia* case of obviousness has not been established as the applied references fail to teach each and every element of the claims.

Applicant submits that neither LEBNER nor BAKER disclose or suggest the combination of features recited in the at least independent claim 1 and claim 19, as currently amended. Applicant also submits that no proper combination of these documents disclose or suggest the combination of features recited in at least the independent claims.

As discussed above, LEBNER lacks any disclosure or suggestion with regard to the *average width of the bridging portions being less than the average width of the attached portions*. Indeed, Applicant has demonstrated that the device of LEBNER is different than Applicant’s above-noted instant invention, and that LEBNER does not disclose or suggest the above-noted features of Applicant’s claimed invention.

With regard to BAKER, Applicant acknowledges that BAKER teaches a surgical

incise drape 10 having a film 12 that includes an upper surface 13 and lower surface 15 extending from a leading edge 31 of the flexible film 12 to a trailing edge 32 of the flexible film 12. See Figures 1-3 and Col. 5, lines 31-42. However, the Examiner must acknowledge that BAKER lacks any disclosure or suggestion with regard to the combination of features recited in independent claim 1 and claim 19, as currently amended.

Moreover, in addition to failing to disclose the combination of features recited in the independent claim 1 and claim 19, as currently amended, Applicant submits no proper combination of these documents disclose or suggest the combination of features recited in either of the independent claim 1 and claim 19, as currently amended, or in the above-noted claims that depend from the respective independent claim 1 and claim 19, as currently amended.

Accordingly, Applicant respectfully submits that the above-noted rejection under 35 U.S.C. § 103(a) should be withdrawn.

CONCLUSION

In view of the foregoing, it is submitted that none of the references of record, either taken alone or in any proper combination thereof, anticipate or render obvious Applicant's invention, as recited in each of claims 1-36. The applied references of record have been discussed and distinguished, while significant claimed features of the present invention have been pointed out.

Further, any amendments to the claims which have been made in this response and which have not been specifically noted to overcome a rejection based upon the prior art, should be considered to have been made for a purpose unrelated to

patentability, and no estoppel should be deemed to attach thereto.

Accordingly, reconsideration of the outstanding Office Action and allowance of the present application and all the claims therein are respectfully requested and now believed to be appropriate.

Respectfully submitted,
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